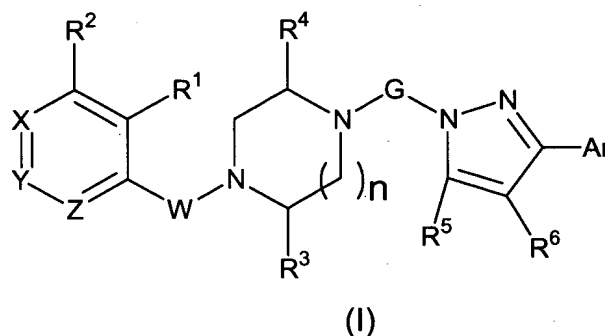


REMARKS

Applicants thank the Examiner for including in the Office Action the previously filed PTO1449 forms, now with the references therein of record, and also for acknowledging the amendments submitted with Amendment and Response "B" on April 29, 2004, which are understood as having been entered in the records of the present application.

Claims 43-45 of co-pending application US 09/928,122 (hereinafter the "'122 Application") recite methods that comprise administering a composition that comprises a compound recited in claims 1, 30, 31, or 36 therein. Such claims 30, 31, and 36 depend, directly or through other depending intervening claims, from independent claim 1 therein. Such claim 1 recites, *inter alia*, a compound of formula (I)



in which R⁵ and R⁶ are "taken together to form pyridinyl or 5-membered carbocyclic ring or 7-membered carbocyclic ring, which ring may be unsaturated or aromatic, and each of said pyridinyl, 5-membered ring and 7-membered ring may be optionally substituted with ...". The '122 Application, Amendment and Response "B", filed May 28, 2004.

The pending claims in the present application recite methods that comprise administering a composition that comprises a compound recited as in the preceding list of pending claims in the present application. These claims provide, *inter alia*, that "each of R⁵ and R⁶ is independently ...; alternatively, R⁵ and R⁶ can be taken together to form optionally substituted 6-membered carbocyclic ring, which ring may be unsaturated or aromatic, and may be optionally substituted with ...".

It follows from at least the quoted recitations of portions of the claims in the '122 Application and portions of the claims in the present application, that such claims recite

different subject matter.

Applicants note that a case that the pending claims are not patentably distinct from the claims in the '122 patent has not been established. Consequently, a double patenting rejection should not be asserted.

Even if, *arguendo*, a subgenus of reference claims were recited herein, note that claims that recited overlapping subject matter in the form of a genus of the compounds in pending claims were not considered support for a nonstatutory double patenting rejection because the genus and sub-genus recited therein were patentably distinct from each other. *See, e.g., In re Sarett*, 327 F.2d 1005 (C.C.P.A. 1964) (reversing all the rejections by the US PTO Board of Patent Appeals and Interferences that had been predicated on nonstatutory double patenting, and holding that the claims in a pending patent application that specifically recited a "pyridine-chromium trioxide complex" as an oxidizing agent were patentably distinct from the claims in an issued patent that generically recited "an oxidizing agent").

In addition, the claims in the present application are not an obvious variation of the claims in the '122 application. As shown above, the claims in the '122 application recite different subject matter than that recited in the present pending claims. Furthermore, there is no showing of record that the presently claimed subject matter could be obtained as an obvious variation of the —different— subject matter recited in the claims of the '122 application.

Applicants respectfully note that

[o]ne significant difference [between a double patenting rejection and rejections based on prior art] is that a double patenting rejection must rely on a comparison with the claims in an issued or to be issued patent, whereas an obviousness rejection based on the same patent under 35 U.S.C. [§§] 102(e)/103(a) relies on a comparison with what is disclosed (whether or not claimed) in the same issued or to be issued patent. In a 35 U.S.C. [§§] 102(e)/103(a) rejection over a prior art patent, the reference patent is available for all that it fairly discloses to one of ordinary skill in the art, regardless of what is claimed. (Citation omitted).

M.P.E.P. § 804.III, p. 800-29, 8th ed. (Aug. 2001). The comparison of the pending claims with claims 43-45 in the '122 Application reveals that they recite different subject matter

and that the pending claims are not obvious variations of the claims in the '122 Application.

The claims in the present Application may not be rejected under the nonstatutory double patenting doctrine in view of claims 43-45 of the '122 Application.

It has been established that "[o]bviousness-type double patenting entails a two-step analysis." *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 55 U.S.P.Q.2d 1609, 1617 (Fed. Cir. 2000).

First, the construed claims are overlaid "to determine whether the later claim encompasses subject matter previously claimed." *Id.*, at 1617. *See also In re Sarett*, 327 F.2d 1005 (C.C.P.A. 1964) (stating with respect to the specifics of a double patenting rejection that "the question is whether the ... invention [recited in the pending claims] is in effect claimed in the issued ... patent [used as a purported basis for a double patenting rejection]", and reversing all the rejections that had been predicated on such ground). As shown herein, the pending claims do not recite subject matter that is recited in claims 43-45 of the '122 Application. Therefore, the answer to the first part of the inquiry on the appropriateness of an obviousness-type double patenting rejection is in the negative.

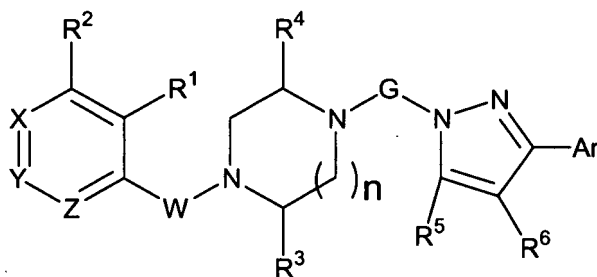
In the second step, it is to be determined "whether the differences in subject matter between the two claims [are] such that the claims are patentably distinct." *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 55 U.S.P.Q.2d 1609, at 1617. In this regard, "double patenting is not 'concerned with what one skilled in the art would be aware [of] from reading the claims but with what inventions the claims define.'" (Preposition added in the original; quotation omitted). *Id.*, at 1618. As shown herein, the pending claims and the claims in the '122 Application recite different subject matter, and they define different inventions. The pending claims must therefore be regarded as patentably distinct from the claims in the '122 Application. Furthermore, no case has been made to show that the pending claims would not be patentably distinguishable from the claims in the '122 Application, particularly in light of the differences between the pending claims and the claims in the '122 Application.

The reason for citing WO 97/40066 is not clear to Applicants. Even if, *arguendo*, such publication were citable, Applicants submit that the foregoing reasoning concerning

presently pending claim recitations in the present application and in the '122 Application renders the nonstatutory double patenting rejections moot.

For at least the foregoing reasons Applicants respectfully submit that the pending claims may not be rejected under the nonstatutory double patenting doctrine in view of claims 43-45 of the '122 Application, and consequently request the removal of these rejections.

Claims 1-8 of co-pending application US 09/947,041 (hereinafter the "'041 Application") recite methods that comprise administering a composition that comprises a compound recited in claims 1-8 therein. Such claims 1-8 depend, directly or through other depending intervening claims, from independent claim 1 therein. Such claim 1 recites, *inter alia*, a compound of formula



in which R⁵ and R⁶ "can be taken together to form an optionally substituted 5- to 7-membered heterocyclic ring, a 5-membered carbocyclic ring, or a 7-membered carbocyclic ring, which ring may be unsaturated or aromatic, and may be optionally substituted with ...". The '041 Application, Amendment and Response "C", filed December 20, 2004.

As noted above, the pending claims in the present application recite methods that comprise administering a composition that comprises a compound recited as in the preceding list of pending claims in the present application. These claims provide, *inter alia*, that "each of R⁵ and R⁶ is independently ...; alternatively, R⁵ and R⁶ can be taken together to form optionally substituted 6-membered carbocyclic ring, which ring may be unsaturated or aromatic, and may be optionally substituted with ...".

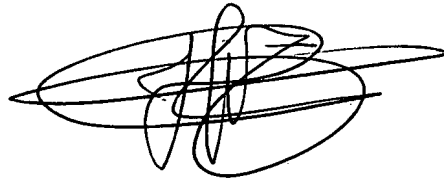
It follows from at least the quoted recitations of portions of the claims in the '041 Application and portions of the claims in the present application, that such claims recite

different subject matter. The reasoning and support provide above in the context of the analysis referring to the '122 Application is re-asserted herein with reference to claims 1-8 of the '041 Application.

For at least the foregoing reasons Applicants respectfully submit that the pending claims may not be rejected under the nonstatutory double patenting doctrine in view of claims 1-8 of the '041 Application, and consequently request the removal of these rejections.

Applicants respectfully request favorable consideration of the present Response to place the present application in condition for allowance.

Respectfully submitted,

A handwritten signature in black ink, consisting of several overlapping loops and a long horizontal stroke extending to the right.

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